REMARKS

Claim 1-22 are pending in this application. Claim 1 is amended herein to include the substituent group definitions of pending claim 3, and claim 3 is canceled. Claims 4-16, 18, 19, 20 and 22 are amended herein to delete multiple claim dependencies. No new matter is added by way of these amendments. Entry of the claim amendments and reconsideration in view of the remarks presented herein are respectfully requested.

Formal Matters

A Supplemental Information Disclosure Statement complying with the requirements of 37 CFR 1.98(b) will be submitted.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-22 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner takes the position that claims to solvates and solvates of salts lack adequate written description. The Examiner further contends that the specification lacks adequate written description to show possession of all the claimed subject matter, and points specifically to certain groups included in the definition of R^1. Applicants respectfully traverse the rejection.

Solely to advance prosecution, the claims are amended herein to delete claim language relating to solvates and solvates of salts. With regard to the Examiner's objection to certain groups falling within the description of R^1, the Applicants believe this basis of rejection is obviated by the claim amendments.

While Applicants believe the issue is moot, for the sake of completeness, the Applicants respectfully note that the present application does not disclose compounds in which R^4 and R^5 form a heterocycle. The Applicants believe the Examiner's comment on page 8, lines 1-2 of the Office Action was meant to refer to compounds (such as Ex. 10) wherein R^5 and R^6 together form a

heterocycle. Applicants note that the amide substituent bearing groups R^5 and R^6 is installed via a standard amide bond forming reaction of an amine of formula (III), HNR^5R^6, with an acid of formula (II). The specification provides examples of primary, secondary and tertiary amides, including substituted and unsubstituted mono- and dialkylamines, benzylic amines, and cyclic amines, such as morpholine and piperidine, and one of ordinary skill would reasonably expect that a wide variety of amines HNR^5R^6 could be successfully used in this reaction. Applicants respectfully submit that in view of the guidance provided by the specification and the examples, one of skill in the art would reasonably conclude that the Applicants were in possession of the claimed invention at the time the application was filed.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1-22 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. 5,843,682 to Clerc et al., which the Examiner characterizes as describing a structurally similar antibacterial compounds which embraces the presently claimed invention. Applicants respectfully traverse the rejection.

The Examiner points to compounds of formula (1) in column 1, lines 21-22 of Clerc et al., where R is $NHCH_2COOH$ and m, n and p are 0, as allegedly rendering the claimed compounds obvious. The Examiner states that the instant claims differ from Clerc et al. in their generic scope, and asserts that "[t]he instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus ...*with the expectation of obtaining additional beneficial compounds.* The instant claimed compounds would have been suggested to one skilled in the art." See Office Action at page 10, ¶ 2. The Examiner further states that "[o]ne having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds *would have been suggested by the reference as a whole*." See Office Action at page 10, ¶ 3. Applicants respectfully

disagree, and submit that this is not the proper analysis in assessing the obviousness of an invention relating to chemical compounds.

The Federal Circuit recently reaffirmed in *Eisai v. Dr. Reddy's Laboratories Ltd.,* 87 USPQ.2d 1452 (Fed. Cir. 2008), that in chemical compound cases, "[o]bviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. *Id.* at 1455 (citing *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007)).

In order to establish a *prima facie* case for obviousness for a chemical compound, the Office must first provide a reasoned identification of a "lead compound", and then provide a motivation that would lead one of ordinary skill in the art to modify the lead compound in a particular way to achieve the compounds claimed by the Applicants. Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness in the instant case.

Clerc et al. disclose peptide antagonists of neurotensin as useful in the treatment or prevention of various diseases and disorders associated with neurotensin, including psychosis, Parkinson's disease, Alzheimer's disease, autism, ulcers, disorders of the intestine motility or certain tumors (*see* column 5, line 66 to column 6, line 9). Clerc et al. do not disclose that these compounds are useful for the treatment of bacterial infections. The Examiner has provided no rationale why one of ordinary skill in the art seeking to prepare antibacterial compounds would select Clerc et al. as a starting point, since this document does not disclose compounds having antibacterial activity.

In addition, the Examiner has provided no basis for the selection of the hypothetical compound of formula (1) in Clerk et al. where R is $NHCH_2COOH$ and m, n and p are 0 as a starting point for the preparation of compounds having antibacterial activity. Applicants respectfully submit that since nothing is known about the properties of such a compound with respect to its antibacterial activities, the presence of antibacterial properties cannot be assumed in other,

structurally similar compounds. Therefore, there is no motivation for one of ordinary skill in the art to select such a compound as a lead when seeking new compounds having antibacterial activity.

Morevoer, the compounds disclosed by Clerc et al. are only remotely structurally related to the compounds of the present invention, and would not fall within the scope of the present claims, nor would the compounds of the present application fall under the scope of Clerc et al. In particular, the compounds of Clerc et al. contain a second macrocyclic ring on the right-hand side of the molecule formed via a 4-hydroxyphenylalaninyl type structure. By contrast, the compounds of the present invention have a singular macrocyclic ring structure, i.e., the biphenomycin-type ring-structure. In addition, the oxidation pattern on the phenyl rings that make up the biphenyl structure of the biphenomycin backbone differs between the claimed compounds and Clerc et al. In particular, the claimed compounds have hydroxy or alkoxy substituents (OR^7, OR^8) in the 4-position on each of the phenyl rings, whereas the compounds of Clerc et al. carry hydrogens at those positions. The compounds of Clerc et al. contain a phenoxy group in the 5-position that forms part of the second macrocyclic ring, and is located at a different position relative to the macrocycle than OR^7 in the claimed compounds (i.e., meta vs. ortho). The compounds of Clerc et al. also contain hydroxy or methoxy groups in the 6-position on each of the right- and left-hand side phenyl rings (i.e., R_5, R_6) that are not present in the claimed compounds.

Even assuming *arguendo* that one of skill in the art started from the hypothetical compound suggested by the Examiner, the Examiner has provided no rationale why one of ordinary skill in the art would modify this compound *in the particular way* required to arrive at the claimed compounds. Applicants note that such modifications would require removal of the second macrocyclic ring and changes in the oxidation pattern on both of the phenyl groups that make up the biphenomycin backbone. There is simply no basis to suggest that such modifications would have been obvious to one seeking to prepare novel antibacterial compounds in view of Clerc et al.

In view of the foregoing remarks, Applicants respectfully submit that the present invention is nonobvious in view of the teachings of Clerc et al. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. 584212002400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 27, 2009

Respectfully submitted,

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